

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: WHITE, JOHN P.
COOPER & DUNHAM
30 ROCKEFELLER PLAZA
NEW YORK, NEW YORK 10112
UNITED STATES OF AMERICA

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 43016-A-PCT	Date of Mailing <i>(day/month/year)</i> 20 APR 1994
International application No. PCT/US94/00757	International filing date <i>(day/month/year)</i> 21 JANUARY 1994
Applicant Sloan-Kettering Institute for Cancer Research	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JULIE KRSEK-STAPLES <i>Julie Warden for</i>
Facsimile No. NOT APPLICABLE	Telephone No. (703) 308-0196

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 43016-A-PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US94/00757	International filing date (<i>day/month/year</i>) 21 JANUARY 1994	(Earliest) Priority Date (<i>day/month/year</i>) 22 JANUARY 1993
Applicant Sloan-Kettering Institute for Cancer Research		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (See Box I).
2. ☐ Unity of invention is lacking (See Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
 - ☐ filed with the international application.
 - ☐ furnished by the applicant separately from the international application,
 - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - ☐ transcribed by this Authority.
4. With regard to the title,
 - ☐ the text is approved as submitted by the applicant.
 - ☒ the text has been established by this Authority to read as follows:
Ganglioside-KLH Conjugate Vaccines with QS-21
5. With regard to the abstract,
 - ☐ the text is approved as submitted by the applicant.
 - ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
 - Figure No. _____ ☐ as suggested by the applicant.
 - ☐ because the applicant failed to suggest a figure.
 - ☐ because this figure better characterizes the invention.
 - ☒ None of the figures.

B x III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

This invention provides a vaccine for stimulating or enhancing the production of an antibody which recognizes a ganglioside in a subject to which the vaccine is administered. The vaccine is comprised of an amount of ganglioside or oligosaccharide portion thereof conjugated to an immunogenic protein effective to stimulate or enhance antibody production in the subject. The vaccine is further comprised of an adjuvant and a pharmaceutically acceptable vehicle. The invention also provides a method of using the vaccine for treating or preventing cancer wherein gangliosides are on the surface or in the stroma of the cancer cells.

INTERNATIONAL SEARCH REPORT

International application No.

T/US94/00757

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61K 45/05, 31/70; A01N 43/08

US CL :424/88; 514/25

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/88; 514/25, 885

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Chem Abstracts, APS, Medline

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,102,663 (LIVINGSTON et al) 07 April 1992, see column 1, lines 22-28.	1-3, 5-12, 18-21, 26-34, 36, and 39-43
Y	Cancer Research, Volume 49, No. 24, Part 1, Issued 15 December 1989, Livingston et al, "Characterization of IgG and IgM Antibodies Induced in Melanoma Patients by Immunization with Purified GM2 Ganglioside", pages 7045-7050, see pages 7046-7048.	1-3, 5-12, 18-21, 26-34, 36, and 39-43
Y	Seminars in Cancer Biology, Volume 2, No. 6, Issued December 1991, Ritter et al, "Ganglioside Antigens Expressed by Human Cancer Cells", pages 401-409, see page 406.	1-3, 5-12, 18-21, 26-34, 36, and 39-43

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

14 MARCH 1994

Date of mailing of the international search report

20 APR 1994

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

Authorized officer

JULIE KRSEK-STAPLES

Telephone No. (703) 308-0196

INTERNATIONAL SEARCH REPORT

International application No.

US94/00757

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Immunobiology, Volume 182, No. 1, Issued December 1990, Ritter et al, "Antibody Response to Immunization with Purified GD3 ganglioside and GD3 Derivatives (Lactones, Amide and Gangliosidol) in the Mouse", pages 32-43, see abstract.	1-3, 5-12, 18-21, 26-34, 36, and 39-43
Y	Journal of Immunology, Volume 146, No. 2, Issued 15 January 1991, Kensil et al, "Separation and Characterization of Saponins with Adjuvant Activity from <i>Quillaja saponaria</i> Molina Cortex", pages 431-437, see page 433.	4, 13-17 and 35
Y	Vaccine, Volume 9, Issued February 1991, Marciani et al, "Genetically-Engineered Subunit Vaccine Against Feline Leukaemia Virus: Protective Immune Response in Cats", pages 89-96, see page 93.	4, 13-17 and 35
Y	US, A, 4,557,931 (IRIE et al) 10 December 1985, see column 1, lines 28-31.	22-25, 37 and 38
A	Cancer Research, Volume 50, Issued 15 July 1990, Fung et al, "Active Specific Immunotherapy of a Murine Mammary Adenocarcinoma using a Synthetic Tumor-associated Glycoconjugate", pages 4308-4314, see page 4312.	1-43